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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,344	04/04/2008	Lawrence Solomon	SLP-036	2815

47888 7590 01/11/2010

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
01/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,344	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/03/2009 has been entered.

Claims 1-7 are cancelled.

Claims 8-13 are currently amended.

Claims 8-13 are pending and currently under consideration.

Withdrawn Rejections

The rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over Lieberman, Herbert (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller, Ehud (U.S. Patent number 3,927,194) is withdrawn in view of Applicant's cancellation of claims 1-7 and Applicant's amendments to claims 8-13.

The provisional rejection of claims 1, 3-7, and 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-11, 13-18, of copending Application No. 11/441455 is withdrawn in view of Applicant's cancellation of claims 1 and 3-7, and Applicant's amendment to claim 10.

New Grounds of Objections/Rejections

Specification

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US05/18632, filed 5/23/2005, 60/573,042, filed 5/21/2004 and 60/573,134, filed 5/21/2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is

accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 recite the limitation "the distance" in reference to the score. There is insufficient antecedent basis for this limitation in the claim.It is unclear what the phrase "the distance" is referring to. Said distance could be referring to the depth of the score through the first or second segment, OR the depth of the score through the first and second segment, OR the distance from the bottom of the score to be bottom of the tablet, OR the distance from the edge of the tablet to score (i.e. allowing for 70% and 30% dosages). Said recitation does not clearly set forth what Applicant is intending to include and exclude from the instant claims.

Claim 11 is rejected for depending from indefinite claims 9 and 10, which also further lack antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980) and Geller (U.S. Patent number 3,927,194, Patent issued Dec. 16, 1975)

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under "IV. Layer Tablets"). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Lieberman further teaches that the purpose of a score is "to permit breaking the tablet into equal parts for the administration of half a tablet" (see point number 4 under "Properties of Tablets").

Lieberman fails to directly teach that there are only two layers to the tablet, or the particular location of the score, or the instant active ingredient.

Ullman teaches a multi-fractionable unitary tablet structure. The tablet has a score which transverses the entire tablet (note 112 second paragraph rejection of claims 9 and 10 above).

Geller teaches deeply scored tablets wherein the active ingredient is isosorbide dinitrate (see column 2, lines 28-33). Geller further identifies the art recognized deficiency in scored tablets i.e. "scores do not always assure precise division of the tablet" (see column 1, lines 40-41).

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into two separate dosages. There would be a reasonable expectation of success since both Lieberman and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It further would have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which

comprises two incompatible drugs separated by a barrier layer, to remove one of the drug layers of the composition of Lieberman and Ullman, should one desire to only deliver one of the actives, such as is taught in Geller, namely a scored tablet with only one active. One would have been motivated to retain the inert barrier layer since said barrier layer has allowed for the overcoming of the well known problem in the art of variable dosages. There would be a reasonable expectation of success since the removal of one of the actives would not affect the dosage of Lieberman and Ullman. It is further noted that removal of one of the actives is clearly obvious if one only desires to deliver one active, see MPEP 2144.04, which states: "Omission of an element and its function is obvious if the function of the element is not desired *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize drugs directed towards the treatment of cardiovascular conditions in the tablet of Lieberman in view of Ullman. One would have been motivated to do so since Geller teaches that it is useful to be able to provide divided doses of isosorbide dinitrate. There would be a reasonable expectation of success in the use of isosorbide dinitrate since as is seen by Geller, isosorbide dinitrate is known to be advantageously administered by tablets which can be broken into smaller dosing units.

With regard to the "distance" of the tablet, it is noted that Ullman teaches scores which completely transverse the tablet, and therefore, would encompass the limitation of "no less than 70%". It is further noted that depending on the amount of active desired would affect the depth of the score. Should one desire more active, the depth of the score would be greater to allow for breakage of as little of the active layer as is possible. This renders the 50-99.5% range obvious

over both the potential interpretations of the percentage being directed to the depth of the score with regard to the entire tablet, and over the percentage being directed to the depth of the score with regard to the active layer alone.

Response to Arguments

Though the rejections which Applicant's arguments are directed to have been withdrawn, since Lieberman and Geller are still being relied upon, the pertinent arguments are still being addressed.

Applicant points out in the remarks filed 11/16/2009 that Lieberman does not teach or suggest the use of only two layers as required by the instant claims. Applicant argument has been fully considered but is not found persuasive since, as can be seen above, the clear motivation of the variability of doses caused by traditional tablet breakage in Lieberman, and the tablet structure taught by Ullman, one would have been motivated to overcome the disadvantage clearly identified in the art by utilizing the composition of Ullman with an inactive layer as a middle segment through which tablet breakage occurs, thereby allowing more accurate dosing. It further is noted that MPEP 2144.04 clearly identifies that if a component is not desired, it is obvious to eliminate said component, such as an additional active or layer. Applicant argues with regard to Geller that the score distance of Geller is not able to be combined with the teachings of Lieberman since Geller is directed to a unitary dosage and Lieberman is directed to a trilayered tablet. Applicant's arguments are not found persuasive since first, Geller is not longer being relied upon for the teaching of the score depth, and second, Lieberman clearly teaches motivation to score tablets, which include layered tablets, and therefore, Applicant's argument is not found persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 53 of copending Application No. 10/598,355.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and '355 are directed to a bilayered tablet wherein the first layer comprises active and the second layer is substantially free of drugs. Both compositions are score, and are designed to be broken and administered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643